



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Call for Participation for Computational Photography Project for Pill Identification
(C3PI)**

ACTION: Notice

SUMMARY: The National Library of Medicine (NLM) invites pharmaceutical manufacturers, re-packagers, wholesalers, and retail and institutional pharmacies to submit prescription drug products for imaging as part of its Computational Photography Project for Pill Identification (C3PI). The NLM is developing the C3PI oral solid dosage formulations (OSDFs) collection as part of an initiative to build a reliable and high-quality image catalog of all OSDF prescription products marketed in the United States. Such a resource can support a number of public safety initiatives, such as in poison control, emergency response, and reduction of medication errors.

FOR FURTHER INFORMATION: Any question regarding this process or the Computational Photography Project for Pill Identification (C3PI) should be sent to:

splimage@nlm.nih.gov

SUPPLEMENTARY INFORMATION: The Computational Photography Project for Pill Identification (C3PI) aims to develop information infrastructure and computational tools for identifying pills from digital photographs and associated data. As part of C3PI, the NLM has imaged and currently hosts a growing collection of more than 2,000 validated images of pharmaceutical OSDFs. High quality images of these products, photographed using visible spectrum macrophotography techniques, are available for public access through an Applications Programming Interface (API) [<http://RxImage.nlm.nih.gov/>]. These images are also displayed in several NLM drug applications, including RxNav [<http://rxnav.nlm.nih.gov/>] and Pillbox [<http://pillbox.nlm.nih.gov/>].

NLM assisted the FDA in the development the current SPLIMAGE file specification [<http://dailymed.nlm.nih.gov/dailymed/splimagespec.cfm>], which was published in 2012 for submitting image files of oral solid dosage forms to the Food and Drug Administration (FDA) with Structured Product Label (SPL) documents. As part of the ongoing initiative to improve access to quality drug information, the NLM has worked closely with FDA's Center for Drug Evaluation and Research and Office of the Commissioner to increase the number of SPLIMAGE files included in SPL submissions. C3PI has successfully produced more than 2,000 SPLIMAGE files and these SPLIMAGE files have been made available through an NLM portal: <http://SPLimage.nlm.nih.gov>.

NLM is seeking the collaboration of pharmaceutical manufacturers, re-packagers, wholesalers and pharmacies to obtain physical samples of OSDF products whose origin can be traced back to pharmaceutical manufacturers or private label distributors registered or listed with the Food and Drug Administration (FDA). The NLM will

produce SPLIMAGE files suitable for inclusion in submissions to the Food and Drug Administrations' Structured Product Labeling (SPL) program [http://www.fda.gov/forindustry/datastandards/structuredproductlabeling/default.htm]. A secure online portal will be used to make SPLIMAGE files available to participants responding to this Federal Register notice.

C3PI will also support computer vision research. NLM computer scientists are seeking object identification metrics and methods that are invariant with respect to camera angle, lighting, and the color transfer functions often found in digital cameras. The comprehensive collection of images will serve as foundation for research in content-based information retrieval and image-based search in an area of healthcare that directly impacts public safety: safe medication identification and management. In addition to image data, C3PI is generating information on color classification, image segmentation, pill description and dimensions, as well as other metadata.

C3PI is led and managed by NLM's Office of High Performance Computing and Communications in the Lister Hill National Center for Biomedical Communications. Additional information on NLM's Office of High Performance Computing and Communications is available at: <http://lhncbc.nlm.nih.gov/branch/office-high-performance-computing-and-communications>. Information on the Lister Hill National Center for Biomedical Communications is available at: <http://lhncbc.nlm.nih.gov/>.

General Instructions for participating in C3PI

To participate in C3PI please visit <http://SPLImage.nlm.nih.gov> and follow the specific instructions provided. General instructions follow below:

1. Pharmaceutical manufacturers, private label distributors, re-packagers, wholesalers, and retail or institutional pharmacies (Participants) interested in submitting OSDF products to be imaged as part of the NLM sponsored C3PI OSDF Imaging initiative must first communicate their intention to participate in the project by contacting the NLM Point-of-Contact (NLM-PoC) using one of the following means:

Email: splimage@nlm.nih.gov

Or mail to: The National Library of Medicine, C3PI Imaging Initiative, Building 38A, Room B1N-30, 8600 Rockville Pike, Bethesda, MD 20894.

2. NLM-PoC will acknowledge the Participant's communication of intent and will provide the Participant with the necessary DEA and State Licensing documents to allow for the secure shipment of OSDF products to the NLM imaging facility.
3. Prior to shipping OSDFs to the NLM imaging facility, the Participant will provide the NLM-PoC a detailed and complete list of prescription drug products that they intend to submit to NLM for processing and imaging.
4. After the NLM-PoC has authorized the shipment of the prescription drug products in writing, the products will be sent to the address provided by the NLM-PoC. In order for NLM to accept the shipment, the participant must provide NLM-PoC with written confirmation for the shipment, including: (a) shipping manifest details, (b) shipping service used, (c) tracking number, and (d) expected date of arrival.
5. NLM will have a licensed pharmacist review the received contents and match them against the shipment manifest provided the NLM-PoC. NLM-PoC will acknowledge receipt of shipment within 72hrs of its arrival at the appropriate location and will provide

the Participant with an estimate of the date by which OSDF SPLIMAGE-candidate files will become available through the secure online portal: <http://SPLimage.nlm.nih.gov>.

Previous NLM Imaging Initiative Superseded

This notice supersedes all prior instructions provided by 76 FR 29773 - 29775 <https://federalregister.gov/a/2011-12629>, published on May 23, 2011.

Dated: September 12, 2014

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